

Patent

Attorney's Docket No. 017753-128

#23

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Max ROMBI) Group Art Unit: 1651
Application No.: 09/601,019) Examiner: P. Patten
Filed: October 17, 2000) Confirmation No.: 4184
For: COMPOSITION FOR TREATING)
OBESITY AND ESTHETIC)
TREATMENT PROCESS)

TECH CENTER 1600/2900

JAN 16 2003

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DECLARATION BY MAX ROMBI PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Max Rombi, declare and state as follows:

1. I reside in Bordighera, Italy.
2. I have a Doctorate in Veterinary Medicine (D.V.M.).
3. I am the sole inventor of the above-identified patent application.
4. In 1980, I was involved in the creation of Laboratoires ARKOPHARMA,

pharmaceutical company, which is ranked number 1 in Europe on the Nutraceuticals Market and on the Stock Exchange Second Market since 1996.

5. My *curriculum vitae* is attached as Exhibit 1.

6. I have invented a new green tea extract with unexpected synergistic thermogenic effects by optimizing the level of caffeine and catechols in green tea extracts. These synergistic thermogenic effects make the present invention ideal for treating obesity, weight loss, and maintaining an ideal body weight.

*Considered
3/4/03
P.P.*

7. The green tea extracts of the present invention are novel and unobvious because not all green tea extracts result in the synergistic levels of caffeine and catechols.

Moreover, not all extraction methods result in the synergistic levels of caffeine and catechols.

8. It is well known that all teas (black, green, and oolong) derive from the *Camellia sinensis* plant. However, there are at least hundreds of different varieties and botanical types of these three types of tea, e.g., Assamica, Macrophylla, Yunnan, Guangdong, Viridis, and Sinensis. These types of tea plants may contain widely varying amounts of both caffeine and catechols. Catechol content is assessed by measuring the amount of epigallocatechol gallate (EGCG). The experiments described below in Tables 1 and 2 were done under my direction and supervision.

9. Table 1 shown below demonstrates the different dried extract content of different botanical types of tea plants, prepared with 80% ethanol extraction. As can be seen from Table 1, despite the fact that several green teas were extracted in the same fashion, only one of the green teas produces the synergistic thermogenic proportions of caffeine and catecholamines according to the present invention.

Table 1.

| Type of Tea Plant | Caffeine | Catechines |
|-------------------|----------|------------|
| Assamica Type | 6.0% | 24.4% |
| Chakra Type | 7.0% | 17.5% |
| Mandiri Type | 4.6% | 14.7% |
| Gunung Type | 5.7% | 6.5% |

| | | |
|---------------|------|------|
| Sidmanik Type | 5.3% | 3.0% |
|---------------|------|------|

10. In addition to the importance of the type of green tea used, the type of extraction solvent plays a critical role. Depending on the extraction solvent used, the amounts and proportions of the extract will markedly vary. As shown in Table 2, below, varying the type of extraction solvent results in different levels of caffeine and catechols in extracts of Assamica type green tea.

Table 2.

| Alcohol Content | Caffeine | Catechines |
|-----------------|----------|------------|
| 100% Ethanol | 8.35% | 22.0% |
| 80% Ethanol | 6.0% | 24.4% |
| 70% Ethanol | 5.5% | 19.7% |
| 50% Ethanol | 5.1% | 18.3% |
| 30% Ethanol | 4.8% | 17.9% |
| 50% Methanol | 5.7% | 20.0% |


11. Thus, it is readily seen that differing levels of caffeine and catechols can be obtained by varying either the type of tea used and/or the extraction solvent. Accordingly, only certain extractions of certain tea types will end up yielding the synergistic proportions of caffeine and catechols, not just any green tea extract. The results in Tables 1 and 2 further demonstrate that it cannot be assumed or predicted that a particular green tea will have the synergistic thermogenic amounts or proportions of caffeine and catechols, even if

the same extraction solvent exemplified in the specification, 80% ethanol, is used. Prior to the present invention, the synergy of this particular combination of caffeine and catechols was unknown. Therefore, the present invention allows one skilled in the art to generate these novel green tea extracts using routine extraction and detection methods.

12. Moreover, the present invention is non-obvious as evidenced by its commercial success shown in the attached Exhibit 2. Exhibit 1 is a recent letter I received from a division of Arkopharma detailing recent sales for a green tea extract according to the present invention, AR-25, as described in the present specification. As can be seen from the letter, sales of AR-25 to Alpine Health from August 28, 2002 to November 12, 2002, total 17,360 kg for \$ 677,040. Moreover, Alpine Health has projected that their projected needs for AR-25 for December 2002 and through the first quarter of 2003 will total 40,000 kg! Accordingly, the novel green tea extract AR-25 is experiencing commercial success.

14. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

6/01/2003
Date



Max Rombi

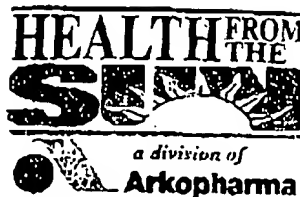


EXHIBIT 1

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November 14, 2002

Dr. Max Rombi
Arkopharma

Dear Dr. Rombi,

As mentioned in your memo, business is getting better and better. We just finalized a great month of October with record sales of branded products with profit to match. November is also looking good so far.

As requested, you will find attached the invoices to Alpine Health for sales of our Green Tea Extract AR-25 they are:

| <u>Invoice#</u> | <u>Date</u> | <u>Quantity</u> | <u>\$ Amount</u> |
|-----------------|--------------|-----------------|-------------------------|
| IV38192 | 8/28/02 | 120 | \$ 4,680 |
| IV38191 | 8/28/02 | 5,000 | \$ 195,000 |
| IV38430 | 9/05/02 | 5,120 | \$ 199,680 |
| IV38667 | 9/12/02 | 5,120 | \$ 199,680 |
| IV41091 | 11/12/02 | 2,000 | \$ 78,000 |
| | Total | 17,360 | Total \$ 677,040 |

We also currently have an order for an additional 5,760 kg to be delivered towards the end of November.

Their forecast for the rest of 2002 and the first quarter of 2003 is as follows:

| | |
|---------------|-----------|
| December 2002 | 3,500 kg |
| January 2003 | 18,000 kg |
| February 2003 | 7,500 kg |
| March 2003 | 11,000 kg |

ARKOPHARMA, LLC dba HEALTH FROM THE SUN

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